DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 4,2014

Cavex Holland BV
Mr. Richard Woortman
Manager Technical Services
Fustweg 5
Haarlem 2031CJ
THE NETHERLANDS

Re: K141092
Trade/Device Name: MARK3 Alginate Impression Material
Regulation Number: 21 CFR 872.3660
Regulation Name: Material, Impression
Regulatory Class: II
Product Code: ELW
Dated: October 28, 2014
Received: November 14, 2014

Dear Mr. Woortman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K141092

DEVICE NAME: **MARK3 Alginate Impression Materials**

INDICATIONS FOR USE:

MARK3 is an irreversible hydrocolloid dental impression material used by the dentist for taking impressions of the oral cavity with the purpose of constructing a gypsum cast that is a copy of the situation in the mouth. It is a general purpose impression materials for making study models, first impressions for the construction of individual trays, situation models, orthodontic impressions.

Prescription Use_X_ (Per 21 CFR 801.109) OR Over-The-Counter-Use____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

_____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Date: 2014 December 04

K141092

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Submitter/Manufacturer:	**Cavex Holland BV**
Establishment:	Fustweg 5, 2031CJ Haarlem, The Netherlands
Registration number:	9614573
Owner/operator number:	9033296
Primary Contact Person:	Richard Woortman Manager Technical Services Cavex Holland BV Phone: +31 (0)235307700 Email: r.woortman@cavex.nl
Distributor / Importer:	**Cargus Int'l, Inc.**
Establishment:	135N Rt. 9w, Congers, NY 10920, USA
Registration number:	2437780
Owner/operator number:	9033437
Official Correspondent:	Bryan Markiet 135N Rt. 9w, Congers, NY 10920, USA Phone: 845-2672600
Device:	
Trade name:	Mark3 Alginate Impression Material
Common use:	Impression Material
Classification Names:	Material, Impression
Regulation Number:	CFR 872.3660
Product Code:	ELW
Primary Predicate:	K981970
Secondary Predicate:	K011419, K051207, K013336, K023466, K032116

Device Description:

MARK3 alginate impression material is a dust free alginate impression material with a creamy consistency for general dental practice and for orthodontics. It is presented in the form of a homogeneous pink colored powder with nice mint flavor. The material has exceptional good elastic properties and a high tear-resistance. The impression surface is smooth, which gives excellent gypsum compatibility

Intended Use:

MARK3 is an irreversible hydrocolloid dental impression material used by the dentist for taking impressions of the oral cavity with the purpose of constructing a gypsum cast that is a copy of the situation in the mouth. It is a general purpose impression materials for making study models, first impressions for the construction of individual trays, situation models, orthodontic impressions.

Technical Characteristics:

The technology for the proposed device MARK3 is comparable to the predicate devices.

Basically the alginate, a soluble salt of alginic acid (extracted from brown seaweed), serves as the thickener for water, giving the paste, upon mixing, the correct consistency.

It also reacts chemically with calcium sulphate to make the paste harden into a solid impression.

The fillers (diatomaceous earth) give the mixture its mechanical strength and proper handling characteristics.

A retarder, sodium pyrophosphate, is used for achieving the proper hardening-time. Sufficient working time to mix, apply and take a proper impression and short setting time in the mouth.

Stabilizers will improve the surface-smoothness of the gypsum-cast and the pigment facilitates the "reading" of the impression by the dentist for a good judgment of its quality.

Peppermint oil is added to overcome the "gagging" reflex which can occur during the impression taking.

Paraffin oil is added in order to prevent dust formation during dosing and mixing of the powder.

Performance Data:

Physical Parameters	Proposed device	ADA18 Requirements
	K141092	
	MARK3	
Appearance	Powder	
Color	Pink	
Compatibility & Detail Reproduction	Complies	0 - 50 µm
Recovery from Deformation	Complies	>95 %
Strain in Compression	Complies	5 - 20 %
Compressive Strength	Complies	> 0.35 Mpa
Deterioration	Complies	> 0.294 MPa

Biocompatibility:

MARK3 alginate impression material, primary predicate device and secondary devices contacts directly with the oral mucosa (3 – 5 minutes) therefore they are categorized as surface contact devices with limited contact duration. Testing is performed for cytotoxicity (ISO19993-5), sensitization and irritation (ISO10993-10). The test results demonstrated that the proposed device MARK3 is biocompatible.

Conclusion:

The technical characteristics, material composition, principles of operation and indications for use of the proposed device MARK3 alginate (K141092) is comparable to several secondary devices. Therefore, Cavex Holland BV considers the MARK3 Alginate Impression Material to be as safe, as effective and performance substantially equivalent to the predicate devices.

eCopy Statement:

The eCopy is identical to the paper copy

Richard Woortman
Manager Technical Services
Cavex Holland BV